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(54) ULTRASOFT EMBOLISM DEVICES

ULTRAWEICHE EMBOLIEVORRICHTUNG

DISPOSITIFS D'EMBOLIE ULTRASOUPLES

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Description

This invention is a flexible, vaso-occlusive or embolism forming device. It is made of a coil which forms a long, thin threadlike device having little rigidity or column strength. The diameter of the device is less than about 0.25 mm (0.010 inches). The filamentary material making up the device used to form the coil is typically of a diameter less than about 0.051 mm (0.002 inches). The device is sufficiently flexible and small that it may be hydraulically delivered to a site within the vasculature of the human body using an injected drug or fluid flush through a catheter. In some configurations, the device may be delivered using pushers to mechanically deliver the device through the catheter lumen. Various mechanical connections may be used to sever the coil but a simple connection of a dissimilar metal to allow electrolytic separation upon application of a small voltage is desirable. The device assumes a random mass of threadlike material after being ejected from the catheter tip at the chosen vascular site. The coil may be a single or of multiple helices. The device may be used alone or in conjunction with larger coils or braids to achieve a denser occlusion or with fibrous thrombotic attachments or as a substrate to localize the subsequent infusion of tissue adhesives, particulate embolization devices, or chemotherapeutic agents in abnormal blood vessels and tissues. The device may be used for the temporary occlusion of blood vessels during types of diminished blood flow testing.

Endovascular therapy has been used in treating a variety of different conditions, including control of internal bleeding, occlusion of blood supply to tumors, and relief of vessel wall pressure in the region of aneurysm. A variety of different embolic agents are known as arguably suitable for such therapy.

One known embolic agent includes injectable fluids or suspensions, such as microfibrillar collagen, various polymeric beads, and polyvinyl alcohol foam. The polymeric agents may be additionally crosslinked, sometimes *in vivo*, to extend the persistence of the agent at the desired vascular site. These agents are often introduced into the vasculature through a catheter. After such introduction, materials there form a solid space-filling mass. Although they provide good short-term vaso-occlusion, they are ultimately reabsorbed in the process of vessel recanalization.

Polymer resins, typically cyanoacrylates, are also employed as injectable vaso-occlusive materials. The resins are typically mixed with a radio-opaque contrast material or made radiopaque by the addition of tantalum powder. Their use is fraught with problems in that placement of the mixture is quite difficult. Inadvertent embolisms in normal vasculature (due to the inability of controlling the destination of the pre-gelled resins) is not altogether uncommon. The material is also difficult or impossible to retrieve once it has been placed in the vasculature. Such resins have not been FDA approved, and a waiver must be reguested in each instance where the materials are applied during human operative procedures.

A number of mechanical vaso-occlusive devices are widely used. One such device is a balloon which may be carried to the vessel site at the end of the catheter and there inflated with a suitable fluid, typically a polymerizable resin, and released from the end of the catheter. The balloon device has the advantage that it effectively fills the cross-section of the occluded vessel. However, when using intravascular balloon embolization of intracranial berry aneurysms, inflation of a balloon into the aneurysm carries some risk of aneurysm rupture due to possible "overfilling" of portions of the sac and due to the traction produced when detaching the balloon from the end of the catheter. Moreover, a vascular balloon is difficult to retrieve after the resin within the balloon sets up, and the balloon cannot be easily visualized using radiographic techniques unless it is filled with contrast material. Balloons have also been known to rupture during filling, or release prematurely during filling, or leak monomeric resin into the vasculature during the period before the monomer sets up into polymeric form.

Another type of mechanical vaso-occlusive device is a wire coil or braid which can be introduced through a catheter in stretched linear form and assumes an irregular shape upon discharge of the device from the end of the catheter. A variety of vaso-occlusive coils and braids are known. For instance, U.S. Patent 4,994,069, to Ritchart et al. and upon which the preamble of claim 1 is based, shows a flexible, preferably coiled, wire for use in small vessel vaso-occlusion. Unlike vaso-occlusive coils previously, Ritchart et al. teaches a coil which is fairly soft and is delivered to the site using a pusher within a catheter lumen. The Ritchart et al. coils are typically pushed into the desired vascular site in a linear configuration. Upon discharge from the catheter, the coil may undertake any of a number of random or regular configurations designed to fill the site. The coils are used for small vessel sites, e.g., 0.5-6 mm in diameter. The coils themselves are said to be between 0.25 and 0.76 mm (0.010 and 0.030 inches) in diameter. The length of the coiled wire is typically 15-20 times the diameter of the vessel to be occluded. The wire used to make up the coils may be 0.05 and 0.15 mm (0.002 to 0.006 inches) in diameter. Tungsten, platinum, and gold threads or wires are said to be preferred. These coils have a variety of benefits, including the fact that they are relatively permanent, they can be easily imaged radiographically, they may be located at a well-defined vessel site, and they can be retrieved.

A variation of the mechanical endovascular coil is the electrolytically detached endovascular coil described in U.S. Patent 5,122,132, to Guglielmi et al. Guglielmi's coils are typically used in intracranial aneurysms because of their effectiveness in quickly forming controlled emboli. The disclosed coils are similar to those of Ritchart et al. in size and in composition. However, the method of introducing the coil to the vascular site is somewhat different. Rather than mechanically thrusting the coil into the chosen site, the coil is placed at the site and a small voltage is applied to the

guidewire supporting the coil so that the coil is electrolytically detached from the distal tip of the guidewire. The step of electrolytically detaching the coil has the added benefit of forming a thrombus as the coil is detached. Again, as noted above, the Guglielmi coils may be stainless steel or platinum or the like, and are typically 0.25 mm to 0.5 mm (0.010 to 0.020 inches) in diameter and are made using wire having approximate diameters of 0.025 mm to 0.127 mm (0.001 to 0.005 inches). The coils in this service are typically between 1 and 50 centimeters in length.

None of this background shows embolism-forming coils, braids, or chains having diameters less than about 0.25 mm (0.010 inches) in diameter, nor their placement by fluid delivery through a catheter.

According to the present invention there is provided a flexible, vaso-occlusive device comprising a coil, characterised in that the flexible coil has an outside diameter less than about 0.25 mm (0.010 inches) and is sufficiently flexible that the free end of a one centimetre length of the coil, when supported horizontally at the opposite end of said length to said free end, will deflect more than about 20° under its own weight.

The hereinafter illustrated and described embodiments of devices in accordance with the present invention are exceptionally flexible, ultrasoft vaso-occlusive or embolism devices. They may be made of a radiopaque material forming a long, thin thread-like device having little rigidity or column strength. The diameters of the devices are preferably less than 0.19 mm (0.0075 inches) in diameter. Wire making up the devices is typically of a diameter less than about 0.051 mm (0.002 inches). The devices are sufficiently flexible and small that they may be hydraulicly delivered to a site within the vasculature of the human body using a catheter. The devices may be mechanically delivered using a pusher wire. The devices may be severed from the pusher wire using a mechanical or electrolytic connection. Because of their flexibility and size there is little opportunity for friction to develop with the catheter lumen.

These devices may be used with guide wire-directed catheters and with flow directed catheters, even those which are very flexible in their distal regions. This invention provides opportunities for placement of embolism-forming devices in vascular regions otherwise not routinely accessible due to their remote nature.

The device typically assumes a loose, random mass after being ejected from the catheter tip at the selected vascular site. When introduced into a high flow region, the mass quickly compacts into a significantly denser mass. The device may be used in conjunction with larger coils, braids, or chains to achieve a denser occlusion or as a substrate to localize the subsequent infusion of tissue adhesives, particulate embolization devices, or chemotherapeutic agents in abnormal blood vessels and tissues, or for the temporary occlusion of blood vessels during types of diminished blood flow testing. The device may be coated with thrombotic or therapeutic materials or used in conjunction with fibrous embolic additions to the device.

In use, one can first introduce a larger vaso-occlusive device, such as a coil, to the vascular site desired by the attending physician, and follow this by the introduction of the inventive device so as to fill the interstices left by the larger coils and thereby form a denser occlusion. The devices may also be introduced by themselves, if so desired.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows an enlarged side view of a coil made according to this invention.

Figure 1B shows an enlarged side view of a double helix coil made according to the invention.

Figure 2 shows an enlarged side view of a braid not in accordance with this invention.

Figure 3 shows an enlarged side view of a combination coil and braid made according to this invention.

Figure 4 is a close-up drawing of a variation of the Figure 3 device in which a braided material is woven on the outside of the coil.

Figures 5A and 5B are close-up views of ends of coils made to use electrolytic separation from a wire pusher.

Figure 6 is a clinical set-up which may be used hydraulically to introduce the coils into the vasculature.

Figure 7 shows a method for mechanically introducing one or more of the inventive devices into the vasculature.

Figure 8 is a graph comparing deflection versus extension for three coils; one coil made according to this invention and two commercially available embolism coils made generally according to the prior art.

Figure 1A shows a coil (100) made according to this invention. It is a fairly straightforward device typically formed by wrapping or winding a fine filament or wire (102), preferably having a diameter (104) less than about 0.064 mm (0.0025 inches), preferably 0.011 mm to about 0.057 mm (0.00045 to about 0.00225 inches), more preferably about 0.013 mm to 0.051 mm (0.0005 to 0.002 inches), most preferably about 0.025 mm to 0.051 mm (0.001 to 0.002 inches), about a spinning mandrel using well-known coil-manufacturing techniques. A separate end cap (108) or termination piece may be included at the end of the coil. The terminator (108) may be a separate piece or a fused portion of the coil or a bit of a filled material such as an epoxy. The major function of the end piece is to prevent the coil from catching on the interior of the catheter lumen or vessel. However, it is acceptable for devices of this size to simply cut the coil ends and not use a terminator (108).

In producing the coil, the coil-manufacturing method is adjusted to produce a single-layer coil typically with a minimum helical pitch, that is to say, the windings are fairly closely packed. Typically, the mandrel will be of such a diameter that the outside coil diameter (106) will be less than 0.25 mm (0.010 inches), preferably 0.036 mm to 0.24 mm (0.0014

to 0.0095 inches), more preferably between 0.1 mm and 0.24 mm (0.004 and 0.0095 inches), and most preferably between 0.1 mm and 0.19 mm (0.004 and 0.0075 inches). The soft, flexible coil thus produced is cut to desired lengths after removal from the mandrel. We have found that the device is especially suitable for the noted service when the device (coil, braid, or combination) deflects more than about 20° (preferably more than about 35°) under its own weight over the first centimeter of length, when supported at a single end. The length of the coil may be between 2 mm and 120 cm, typically between 30 cm and 120 cm.

Instead of the filament shown in Figures 1A and 1B, the coil may be produced from a ribbon whose major axis is between 0.025 and 0.051 mm (0.001 and 0.002 inches) and whose minor axis is between 0.01 and 0.025 mm (0.0004 and 0.001 inches). Coils produced from ribbons are often moderately stiffer than those produced from similarly sized filaments. Smaller diameter coils are often more readily produced.

The regularity of winding shown in Figure 1A is not mandatory; the windings may be irregular or of varying pitch. The coil (100) shown in Figure 1A and 1B (and the variations of the invention which are described below) may be produced from any of a number of different materials. Some portion of the material must be radiopaque so that the coil and its position may be readily monitored within the human vasculature. Suitable materials include biocompatible metals, polymers, and alloys. For instance, biocompatible, radiopaque metals include silver, gold, palladium, platinum, tungsten, iridium, and various stainless steels. Other alloys such as platinum and tungsten (preferably 92% platinum and 8% tungsten) are suitable and, indeed, are often most preferred. The platinum-tungsten alloys desirably have a tensile strength of at least about 180 kpsi and, for a wire of a nominal 0.025 mm (0.001") diameter, have a breaking load of 0.76 N (0.17 lb) with a minimum elongation of 2% measured at a speed of 2.54 cm/min (1.0 in/min). Various biocompatible polymers including polyethylene, polyurethane, polypropylene, and the like are suitable for use in these devices, but, because of their lack of radiopacity, must usually be teamed with a radiopaque marker or filled with a radiopaque filler to allow proper positioning of the coil within the body. Similarly, other inorganic materials such as fibrous carbon are suitable and may be used in the invention.

After formation of the coil, its interior may be filled with a drug material such as a drug concentrate and its ends partially sealed for slow drug release from the coil in an *in vivo* aqueous environment. The ends of the coil may be sealed by a water-soluble plug for storage, if so desired. The coil may also (or alternatively) be coated with a thrombotic or medicinal material.

Figure 1B shows a double helix coil made according to the invention. In this variation, a first coil (110) is wound along with a second coil (112). One of the coils is a fine wire, the second coil may also be a wire or it may be a partially hardened fibrous material, e.g., a material or synthetic fiber, such as Dacron or silk or other thrombotic material. The double helix metallic wire coils made according to this variation of the invention are made using the procedure discussed elsewhere in this document. The double helix coils in which the second coil is a material or synthetic fiber, typically requires some modest heat treatment after winding to set the fiber in the form of its metallic spring colleague. For Dacron or silk, this may be done by steaming the wound spring at reasonably low temperatures, e.g., 150°C (300°F) or so, to form the fiber without fusing it.

Figure 2 shows a braided (or otherwise) woven vaso-occlusive device (200) not in accordance with the invention. The braided occlusive device (200) is tubular and produced by weaving fibers or wires over a mandrel much in the same way the coil of Figure 1 was made. Woven braids of this size are not common but are made according to known techniques. The wire or fibers in this variation of the invention may be any of the radiopaque or polymeric materials noted above, and additionally the braid may be made of a combination of those materials either alone or in combination with other suitable polymeric or filamentary materials such as Dacron, cotton, or other materials. Organic fibers such as silk, Dacron, or cotton provide a ready substrate for clot formation in the interior region of a vessel. Often the radiopaque portion of the coil provides only a way to anchor the coil onto the vessel wall at the site of release.

The Figure 2 braid or woven device (200) is of a diameter (204) similar to the coil (106) in Figure 1. The braid may have a termination piece or section (204) similar in constitution to the analogous portion shown in Figure 1 above. The length of the braid may similarly be 2 mm to 120 cm.

Figure 3 shows a side view of a combination coil/braid vaso-occlusive device according to the invention. This combination is a sequence of coils (302) and braids (304) similar in make-up and size as the devices shown in Figures 1 and 2. Lengths of various coils (302) and braids (304), each often 2 mm to 20 cm in length, are joined together at their respective ends to form the combination device. The overall length of the device, as with those above, may be no more than 120 cm. The device may also have caps or termination pieces (306) on the ends of the device.

Figure 4 shows another variation of a coil/braid combination (400). In this variation, however, as is shown by the cutaway insert, the substrate coil is identical to the coil shown in Figure 1 herein. The braid is woven on the exterior of the coil. In this instance, the braid is more desirably a fibrous material such as Dacron, or cotton. The braid may, however, be a radiopaque material such as the metals and alloys and polymers discussed above. The braid may be joined by welding, melting, or by adhesion to the underlying coil (402).

Figures 5A and 5B show in partial cutaway, side views of coils which may be delivered using a pusher such as a guide wire and may be detached electrolytically using a procedure, such as that found in Guglielmi et al. as discussed

above.

Figure 5A is a very enlarged side view of one embodiment of this invention in which the guide wire (504) and a portion of the coil (506) are shown in a partial cross sectional view. A guide wire (504) which may be coated with TEFLON or other suitable insulating material, which coating is not shown, may be placed within a catheter lumen such as is shown in Guglielmi et al. or as is discussed elsewhere in this document. The guide wire (504) typically has a diameter of 0.25 to 0.5 mm (0.010 to 0.020 inches) diameter in the portion more proximal of the portion shown in the drawing. In the Figure 5A portion, guide wire (504) is tapered at its distal end to a point (508) within coil (506). Guide wire (504) may be joined at one or more locations, e.g., joint (510) at the distal end or joint (512) proximal of the distal end. These joints (510) and (512) may be made by soldering or the like.

Figure 5B shows a similar coil guide wire assembly (502) in which a similar guide wire (516) is introduced actually axially within coil (506). The guide wire (516), in this variation, tapers quickly to a very fine wire portion of (518). The most distal portion of a fine wire (518) is joined with coil (506) at junction of (520). Preferably a second joint (522) is made at the proximal end of fine wire (518). This variation of the invention permits substantially greater flexibility than the variation shown in Figure 5A, at least for the region distal of joint (522). However, the safety factor inherent in having two joints fixing the guide wire or core wire (516) remain in existence.

Because of the significant lack of column strength the coils used and portrayed in Figures 5A and 5B, it may be desirable in some instances to introduce the coil not only using respectively guide wires (504) in Figure 5A and guide wire (516) in Figure 5B as pushers, but also to move these coils along through the lumen of the catheter using an ancillary saline hydraulic push. The coils of (506) are detached from the respective guide wires (504) and (516) by imposition of a direct current to the guide wires from a power supply exterior to the body. The current flow from the coils of (506) within the vasculature site causes a thrombus to form by electrothrombosis. Typically, a DC electric current of approximately 0.01 to 2 milliamps at 0.1 to 12 volts as applied to the guide wire. The thrombus forms often within three to five minutes after the imposition of such a voltage. The voltage flows down the guide wire through the insertion means, e.g., the respective conductive joints (e.g., (510) and (512) in Figure 5A and (520) and (522) in Figure 5B) and through the blood or thrombus. The circuit is completed by a negative pole placed in contact with the skin. The coil is detached from the guide wire by electrolytic decomposition of either the joints or some section of the guide wire. For a coil as small as or involved in these inventive devices, the dissolution by electrolytic action normally will take place in less than four minutes. The time off disintegration may obviously be varied by altering the size of the various portions of the guide wire and the area of the guide wire exposed beyond the insulation. The current level may be altered or the flow of conductive fluids such as saline solution may be introduced to enhance the electrolysis rate.

Each of the variations discussed above, when provided in the proper size range and materials, is an extremely soft and flexible device. These devices exert little if any radial force on the blood vessels into which they are placed. They are sufficiently flexible and small that they may be carried by blood flow after ejection from the distal tip of the catheter by which they are introduced to a narrowing region in the vascular lumen where the device wedges or rolls upon itself and wedges within the blood vessel. The fluid-like properties of the device enables it to conform to the complex geometry of certain fragile, abnormal blood vessels, and in so doing, minimize the risk of causing trauma to or even perforation of those blood vessels. Such flow properties also enable placement of the inventive device at sites in the vasculature currently unreachable by catheterization, such as those within an arteriovenous malformation (AVM).

Although the device is very flexible in all of its configurations, it may be produced having a modest amount off "preform." By "preform" is meant the practice found in Ritchart et al. discussed above, where the coil is bent or crimped in such a way that it assumes a nonlinear shape only after it exits the catheter lumen but passes through the lumen with ease. Such a treatment provides some additional randomness when the coil is placed at its intended site within the vasculature.

Figure 6 shows a setup for hydraulically delivering the devices of this invention to a vascular site. In this instance, the devices -- coils are depicted -- are held in an introducer sheath (702) and delivered through a catheter (712) to the desired site motivated by a syringe (704), containing a suitable fluid. The proximal end (706) of the introducer sheath (702) is connected to the fluid-containing syringe. The distal end (708) of the introducer sheath (702) is introduced to the catheter sidearm accessory (710). The lumen in catheter assembly (712) has been previously cleared of guidewires and other interior constrictions. The plunger on syringe (704) is simply pushed down, and the device within introducer sheath (702) is carried down through catheter (712) to the injection site. After the device is injected to the desired site, additional devices may be injected by swapping another introducer sheath (702) with its related device.

This procedure may be carried out after the catheter has been used to introduce coils of larger size to a particular site. The later introduction of the devices of this invention will enhance the thrombotic potential of the earlier-introduced coil in that the inventive devices will tend to fill the interstices left by the larger coils and achieve a more densely packed occlusion site.

Figure 7 shows a set-up for delivering coils (820) to a vascular site using a guide wire (822) as a pusher. This arrangement uses a catheter (812) optionally in conjunction with a syringe (804) containing a suitable motivating fluid such as saline solution. At the proximal end in this variation, the optional syringe is attached directly to the catheter hub

(810). The guide wire (822) in this variation is shown both extending distally out of the catheter (812) and proximally out of the catheter fitting. A torque device (824) for steering the guide wire or core wire (822) may also be seen. Core wire (822) is in turn attached to power supply (826) at its positive terminal. The negative terminal of power supply (826) is in turn attached to a pad (828) which is applied to the skin to provide a complete circuit to the power supply. The current flows through guide wire (822) to the junction between guide wire (822) and coil (820) (explained in more detail with regards to Figures 5A and 5B above) through the thrombus or blood, through the skin back to the pad (828), and then to the power supply. This is used both to create thrombi and to electrolytically sever coil (820) from core wire (822).

Additionally, these processes may include the step of introducing polymer resins, such as cyanoacrylate resins (particularly n-butylcyanoacrylate) to the intended site after the inventive coils, braids, and chains are in place. Said another way, the inventive devices form a substrate for these tissue adhesives, or particulate embolization materials such as microparticles of polyvinyl alcohol foam, or various chemotherapeutic agents. The catheters suitable for use in introducing these devices are discussed in significant detail in U.S. Patent 4,994,069, to Ritchart et al., as was discussed above.

EXAMPLE

This example demonstrates the significant difference between a preferred embodiment of this inventive coil and similar commercial coils of the type discussed in Ritchart et al. The example shows how much more flexible is the inventive coil than the other coils.

Three coils were measured. Coil A was a coil made according to the invention. Coils B and C are commercially available from Target Therapeutics Incorporated for a variety of uses. The coils' physical descriptions are as follows.

TABLE I

COIL	COIL O.D.	WIRE Dia.	PITCH
A	0.178 mm (0.007")	0.025 mm (0.001")	0.025 mm (0.001")
B1	0.254 mm (0.010")	0.051 mm (0.002")	0.051 mm (0.002")
B2	0.254 mm (0.010")	0.051 mm (0.002")	* 0.051 mm+ (0.002+")
C	0.381 mm (0.015")	0.076 mm (0.003")	0.076 mm (0.003")

* (physically stretched before measuring)

An introducer, a tapered length of tubing having an inside diameter of 0.25 mm (0.010 inches), was taped to an angle template taken from an optical comparator. The respective coils were placed within the introducer and allowed to extend from the tip of the introducer at various lengths. The coils were extended to 1.0 cm and beyond. The introducer was held level and the angle between the tip of the introducer and the end of the coil was measured as a function of the length of the coil extending from the introducer. The results of the tests are shown in Table II below and in Figure 8.

TABLE II				
COIL ⇒ extension (mm) ⇓	A (°)	B1 (°)	B2 (°)	C (°)
1	0.75	0	0	-
2	4.0	2	0	-
3	5.5	2	0	-
4	10.0	2	0	-
5	18.5	2	1	-
6	24.5	2	2	-
7	33.5	2	3.5	-
8	42.5	3	4	-
9	45	3	7	-
10	51	3	13	-
20	69	20	-	26.5
30	80	51	-	47
40	84	65	-	-
50	88	73	-	72

The depicted data for the inventive Coil A and the Coil C are averages of a number of measurements of similar coils.

The relationship between the extension of the coils and their resulting deflection in degrees is shown in Figure 8. It is readily observed that, at a 10 mm extension, the angle of deflection for the inventive coil is about 50°. For the other coils, the deflection is typically only about 10% of that value. Consequently, it may be understood that the bending radius of the inventive coil is much smaller, the force needed to bend the coil is significantly smaller, and consequently the coil will move through tortuous pathways both in the vasculature and in the catheter with significantly more ease than would be observed by the other coils.

Claims

1. A flexible, vaso-occlusive device comprising a coil (100, 300, 400, 506), characterised in that the flexible coil has an outside diameter less than about 0.25 mm (0.010 inches) and is sufficiently flexible that the free end of a one centimetre length of the coil, when supported horizontally at the opposite end of said length to said free end, will deflect more than about 20° under its own weight.

2. The device of claim 1 where the coil (100, 300, 400, 506) is regularly wound.

3. The device of claim 1 where the coil (100, 300, 400, 506) is not regularly wound.

4. The device of any one of the preceding claims where the device deflects more than about 35° under its own weight when a one centimetre length of the coil is supported horizontally at said opposite end.

5. The device of any one of the preceding claims having a preformed shape.

6. The device of any one of the preceding claims additionally comprising means for electrolytically detaching the device from insertion means.

7. The device of any one of the preceding claims where the coil comprises a filament having a diameter (104) of less than about 0.064 mm (0.0025 inches).

8. The device of claim 7, where the coil comprises a filament having a diameter (104) of between 0.011 mm (0.00045 inches) and 0.057 mm (0.00225 inches).

9. The device of claim 8, where the coil comprises a filament having a diameter (104) of between 0.013 mm (0.0005 inches) and 0.051 mm (0.002 inches).

10. The device of claim 9, where the coil comprises a filament having a diameter (104) of between 0.025 mm (0.001 inches) and 0.051 mm (0.002 inches).

11. The device of any one of the preceding claims, where the coil comprises a ribbon having a major axis of 0.025 mm (0.001 inches) to 0.051 mm (0.002 inches) and a minor axis of 0.013 mm (0.0005 inches) to 0.025 mm (0.001 inches).

12. The device of any one of the preceding claims, further comprising a braid.

13. The device of claim 12, wherein lengths of coils and braids are joined together at their respective ends to form a combination device (300).

14. The device of claim 12, wherein the braid is woven on the exterior of the coil (400).

15. The device as claimed in any one of claims 12 to 14, wherein the braid is a platinum braid.

16. The device of any one of claims 12 to 15, wherein the braid has an outside diameter of less than about 0.025 mm (0.010 inches).

17. The device of any one of claims 12 to 16, where the braid comprises wire having a diameter of less than about 0.064 mm (0.0025 inches).

18. The device of claim 17, where the braid comprises wire having a diameter between 0.011 mm (0.00045 inches) and 0.057 mm (0.00225 inches).

19. The device of claim 18, where the braid comprises wire having a diameter of between 0.013 mm (0.0005 inches) and 0.051 mm (0.002 inches).

20. The device of claim 19, where the braid comprises wire having a diameter of about 0.025 mm (0.001 inches).

21. The device of any one of claims 12 to 20, where the braid comprises ribbon having a major axis between 0.025 mm (0.001 inches) and 0.051 mm (0.002 inches) and a minor axis between 0.013 mm (0.0005 inches) and 0.025 mm (0.001 inches).

22. The device of any one of the preceding claims, comprising silver, gold, palladium, platinum, tungsten, iridium, stainless steel, or alloys thereof.

23. The device of claim 22, comprising an alloy of platinum and tungsten.

24. The device of any one of the preceding claims, comprising a biocompatible polymer.

25. The device of claim 24, where the biocompatible polymer is filled with a radiopaque material.

26. The device of any one of claims 1 to 24, additionally comprising a radiopaque marker.

27. The device of any one of the preceding claims where the outside diameter (106, 306) is between 0.036 mm (0.0014 inches) and about 0.24 mm (0.0095 inches).

28. The device of claim 27, where the outside diameter (106, 306) is between 0.1 mm (0.004 inches) and about 0.24 mm (0.0095 inches).

29. The device of claim 28, where the outside diameter (106,306) is between 0.1 mm (0.004 inches) and 0.19 mm (0.0075 inches).

30. The device of any one of the preceding claims, where the length of the device is between 30 cm and 120 cm.

Patentansprüche

1. Biegsame, gefäßverschließende Vorrichtung, umfassend eine Spirale (100, 300, 400, 506), dadurch gekennzeichnet, daß die biegsame Spirale einen Außendurchmesser von weniger als etwa 0,25 mm (0,010 Zoll) besitzt und so biegsam ist, daß sich das freie Ende eines 1 cm langen Abschnitts der Spirale unter seinem eigenen Gewicht um mehr als etwa 20° wegbiegen wird, wenn es an dem dem freien Ende entgegengesetzten Ende des Abschnitts horizontal aufliegt.

2. Vorrichtung nach Anspruch 1, bei der die Spirale (100, 300, 400, 506) regelmäßig gewickelt ist.

3. Vorrichtung nach Anspruch 1, bei der die Spirale (100, 300, 400, 506) nicht regelmäßig gewickelt ist.

4. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der sich die Vorrichtung unter ihrem eigenen Gewicht um mehr als etwa 35° wegbiegt, wenn ein 1 cm langer Abschnitt der Spirale an dem entgegengesetzten Ende horizontal aufliegt.

5. Vorrichtung nach einem der vorhergehenden Ansprüche mit einer vorgeformten Form.

6. Vorrichtung nach einem der vorhergehenden Ansprüche, zusätzlich umfassend eine Einrichtung zum elektrolytischen Ablösen der Vorrichtung von der Einführeinrichtung.

7. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der die Spirale aus einem Faden mit einem Durchmesser (104) von weniger als etwa 0,064 mm (0,0025 Zoll) besteht.

8. Vorrichtung nach Anspruch 7, bei der die Spirale aus einem Faden mit einem Durchmesser (104) zwischen 0,011 mm (0,00045 Zoll) und 0,057 mm (0,00225 Zoll) besteht.

9. Vorrichtung nach Anspruch 8, bei der die Spirale aus einem Faden mit einem Durchmesser (104) zwischen 0,013 mm (0,0005 Zoll) und 0,051 mm (0,002 mm) besteht.

10. Vorrichtung nach Anspruch 9, bei der die Spirale aus einem Faden mit einem Durchmesser (104) zwischen 0,025 mm (0,001 Zoll) und 0,051 mm (0,002 Zoll) besteht.

11. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der die Spirale aus einem Band mit einer Hauptachse von 0,025 mm (0,001 Zoll) bis 0,051 mm (0,002 Zoll) und einer Nebenachse von 0,013 mm (0,0005 Zoll) bis 0,025 mm (0,001 Zoll) besteht.

12. Vorrichtung nach einem der vorhergehenden Ansprüche, des weiteren umfassend eine Litze.

13. Vorrichtung nach Anspruch 12, bei der Abschnitte von Spiralen und Litzen an ihren jeweiligen Enden zu einer Kombinationsvorrichtung (300) verbunden sind.

14. Vorrichtung nach Anspruch 12, bei der die Außenseite der Spirale (400) mit der Litze umflochten ist.

15. Vorrichtung nach einem der Ansprüche 12 bis 14, bei der die Litze eine Platinlitze ist.

16. Vorrichtung nach einem der Ansprüche 12 bis 15, bei der die Litze einen Außendurchmesser von weniger als etwa 0,025 mm (0,010 Zoll) besitzt.

17. Vorrichtung nach einem der Ansprüche 12 bis 16, bei der die Litze aus einem Draht mit einem Durchmesser von weniger als etwa 0,064 mm (0,0025 Zoll) besteht.

18. Vorrichtung nach Anspruch 17, bei der die Litze aus einem Draht mit einem Durchmesser zwischen 0,011 mm (0,00045 Zoll) und 0,057 mm (0,00225 Zoll) besteht.

19. Vorrichtung nach Anspruch 18, bei der die Litze aus einem Draht mit einem Durchmesser zwischen 0,013 mm (0,0005 Zoll) und 0,051 mm (0,002 Zoll) besteht.

20. Vorrichtung nach Anspruch 19, bei der die Litze aus einem Draht mit einem Durchmesser von etwa 0,025 mm (0,001 Zoll) besteht.

21. Vorrichtung nach einem der Ansprüche 12 bis 20, bei der die Litze aus einem Band mit einer Hauptachse zwischen 0,025 mm (0,001 Zoll) und 0,051 mm (0,002 Zoll) und einer Nebenachse zwischen 0,013 mm (0,0005 Zoll) und 0,025 mm (0,001 Zoll) besteht.

22. Vorrichtung nach einem der vorhergehenden Ansprüche, bestehend aus Silber, Gold, Palladium, Platin, Wolfram, Iridium, Edelstahl oder Legierungen derselben.

23. Vorrichtung nach Anspruch 22, bestehend aus einer Legierung von Platin und Wolfram.

24. Vorrichtung nach einem der vorhergehenden Ansprüche, bestehend aus einem biokompatiblen Polymer.

25. Vorrichtung nach Anspruch 24, bei der das biokompatible Polymer mit einem strahlenundurchlässigen Material gefüllt ist.

26. Vorrichtung nach einem der Ansprüche 1 bis 24, des weiteren umfassend einen strahlenundurchlässigen Marker.

27. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der der Außendurchmesser (106, 306) zwischen 0,036 mm (0,0014 Zoll) und etwa 0,24 mm (0,0095 Zoll) beträgt.

28. Vorrichtung nach Anspruch 27, bei der der Außendurchmesser (106, 306) zwischen 0,1 mm (0,004 Zoll) und etwa 0,24 mm (0,0095 Zoll) beträgt.

29. Vorrichtung nach Anspruch 28, bei der der Außendurchmesser (106, 306) zwischen 0,1 mm (0,004 Zoll) und 0,19 mm (0,0075 Zoll) beträgt.

30. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der die Länge der Vorrichtung zwischen 30 cm und 120 cm beträgt.

Revendications

1. Dispositif vaso-occlusif flexible comprenant un serpentin (100, 300, 400, 506), caractérisé en ce que le serpentin flexible a un diamètre extérieur inférieur à environ 0,25 mm (0,010 pouce) et est suffisamment flexible pour que l'extrémité libre d'une longueur d'un centimètre du serpentin, lorsqu'il est supporté horizontalement à l'extrémité de ladite longueur opposée à ladite extrémité libre, s'infléchisse de plus d'environ 20° sous son propre poids.

2. Dispositif selon la revendication 1, dans lequel le serpentin (100, 300, 400, 506) est enroulé de façon régulière.

3. Dispositif selon la revendication 1, dans lequel le serpentin (100, 300, 400, 506) n'est pas enroulé de façon régulière.

4. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le dispositif s'infléchit de plus d'envi-

ron 35° sous son propre poids lorsqu'une longueur d'un centimètre du serpentin est supportée horizontalement à ladite extrémité opposée.

5. Dispositif selon l'une quelconque des revendications précédentes, ayant une forme préformée.

6. Dispositif selon l'une quelconque des revendications précédentes, comprenant de plus des moyens pour détacher électrolytiquement le dispositif de moyens d'insertion.

7. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le serpentin comprend un filament ayant un diamètre (104) inférieur à environ 0,064 mm (0,0025 pouce).

8. Dispositif selon la revendication 7, dans lequel le serpentin comprend un filament ayant un diamètre (104) compris entre environ 0,011 mm (0,00045 pouce) et 0,057 mm (0,00225 pouce).

9. Dispositif selon la revendication 8, dans lequel le serpentin comprend un filament ayant un diamètre (104) compris entre 0,013 mm (0,0005 pouce) et 0,051 mm (0,002 pouce).

10. Dispositif selon la revendication 9, dans lequel le serpentin comprend un filament ayant un diamètre (104) compris entre 0,025 mm (0,001 pouce) et 0,051 mm (0,002 pouce).

11. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le serpentin comprend un ruban ayant un axe principal compris entre 0,025 mm (0,001 pouce) et 0,051 mm (0,002 pouce) et un axe secondaire compris entre 0,013 mm (0,0005 pouce) et 0,025 mm (0,001 pouce).

12. Dispositif selon l'une quelconque des revendications précédentes, comprenant de plus une tresse.

13. Dispositif selon la revendication 12, dans lequel des longueurs de serpentins et de tresses sont réunies les unes aux autres à leurs extrémités respectives de façon à former un dispositif de combinaison (300).

14. Dispositif selon la revendication 12, dans lequel la tresse est tissée à l'extérieur du serpentin (400).

15. Dispositif selon l'une quelconque des revendications 12 à 14, dans lequel la tresse est une tresse de platine.

16. Dispositif selon l'une quelconque des revendications 12 à 15, dans lequel la tresse a un diamètre extérieur inférieur à environ 0,025 mm (0,001 pouce).

17. Dispositif selon l'une quelconque des revendications 12 à 16, dans lequel la tresse comprend un fil ayant un diamètre inférieur à environ 0,064 mm (0,0025 pouce).

18. Dispositif selon la revendication 17, dans lequel la tresse comprend un fil ayant un diamètre compris entre 0,011 mm (0,00045 pouce) et 0,057 mm (0,00225 pouce).

19. Dispositif selon la revendication 18, dans lequel la tresse comprend un fil ayant un diamètre compris entre 0,013 mm (0,0005 pouce) et 0,051 mm (0,002 pouce).

20. Dispositif selon la revendication 19, dans lequel la tresse comprend un fil ayant un diamètre d'environ 0,025 mm (0,001 pouce).

21. Dispositif selon l'une quelconque des revendications 12 à 20, dans lequel la tresse comprend un ruban ayant un axe principal compris entre 0,025 mm (0,001 pouce) et 0,051 mm (0,002 pouce), et un axe secondaire compris entre 0,013 mm (0,0005 pouce) et 0,025 mm (0,001 pouce).

22. Dispositif selon l'une quelconque des revendications précédentes, comprenant de l'argent, de l'or, du palladium, du platine, du tungstène, de l'iridium, de l'acier inoxydable, ou des alliages de ceux-ci.

23. Dispositif selon la revendication 22, comprenant un alliage de platine et de tungstène.

24. Dispositif selon l'une quelconque des revendications précédentes, comprenant un polymère biocompatible.

25. Dispositif selon la revendication 24, dans lequel le polymère biocompatible est rempli d'un matériau radioopaque.

26. Dispositif selon l'une quelconque des revendications 1 à 24, comprenant de plus un marqueur radioopaque.

27. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le diamètre extérieur (106, 306) est compris entre 0,036 mm (0,0014 pouce) et environ 0,24 mm (0,0095 pouce).

28. Dispositif selon la revendication 27, dans lequel le diamètre extérieur (106, 306) est compris entre 0,1 mm (0,004 pouce) et environ 0,24 mm (0,0095 pouce).

29. Dispositif selon la revendication 28, dans lequel le diamètre extérieur (106, 306) est compris entre 0,1 mm (0,004 pouce) et 0,19 mm (0,0075 pouce).

30. Dispositif selon l'une quelconque des revendications précédentes, dans lequel la longueur du dispositif est comprise entre 30 cm et 120 cm.

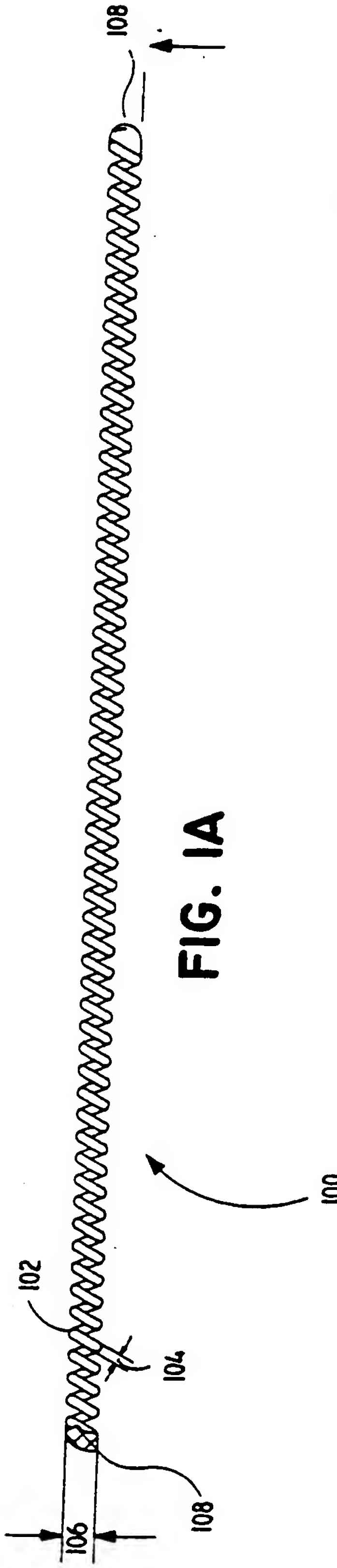

FIG. 1A

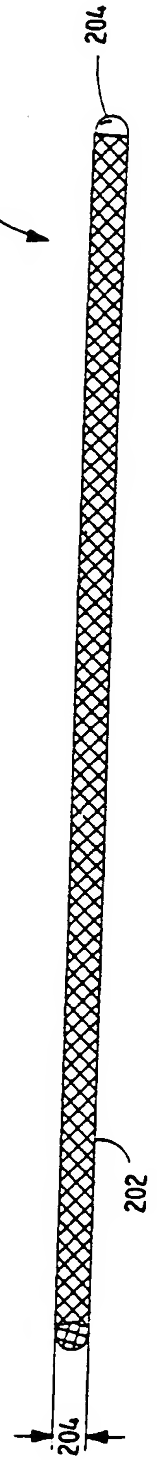

FIG. 2

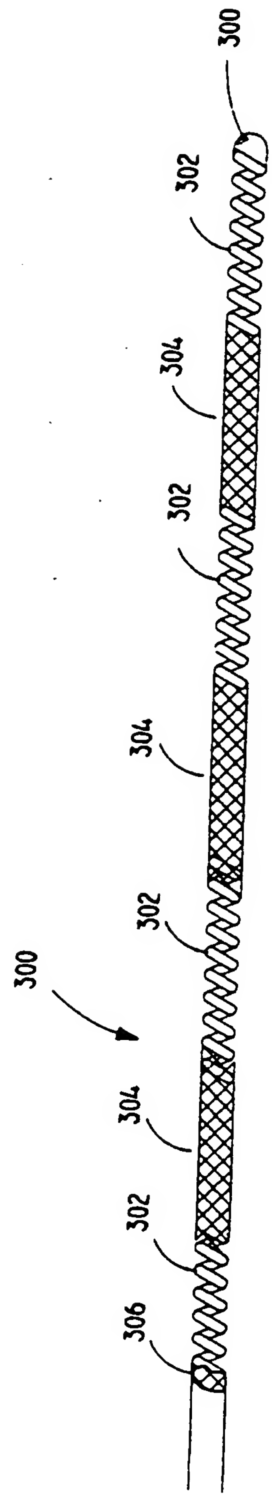

FIG. 3

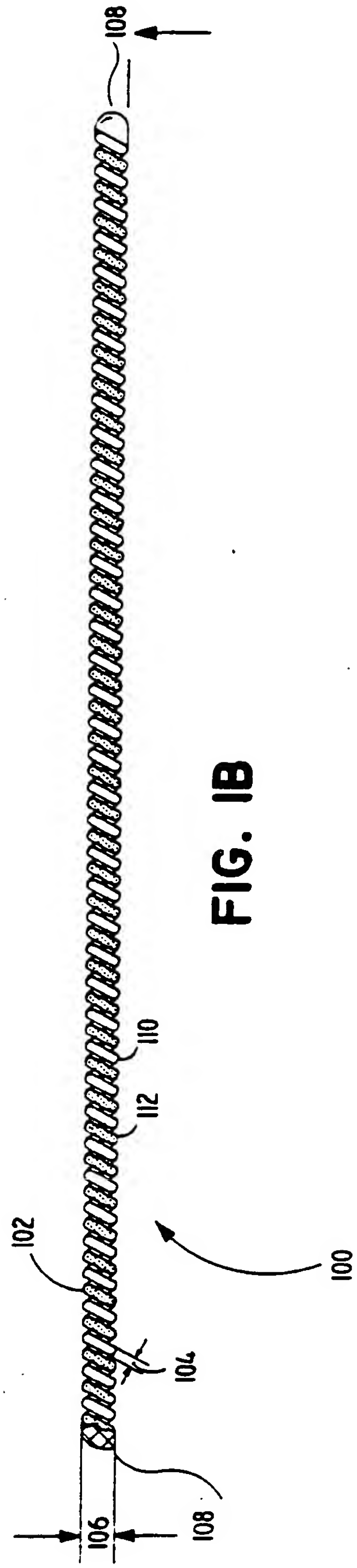

FIG. 1B

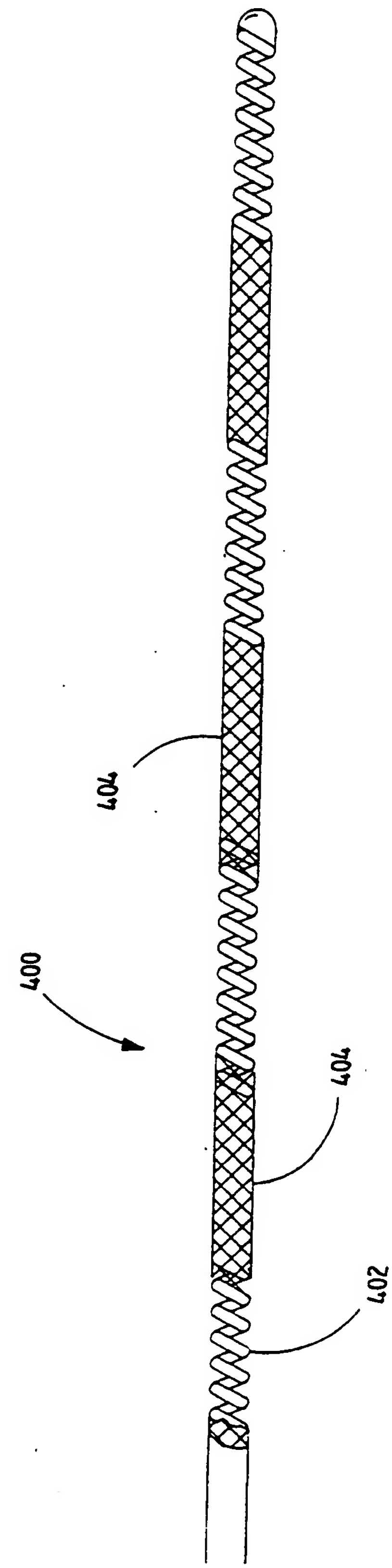

FIG. 4

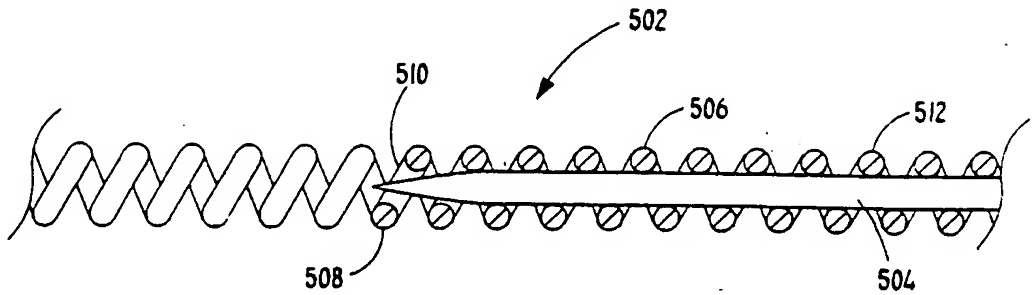

FIG. 5A

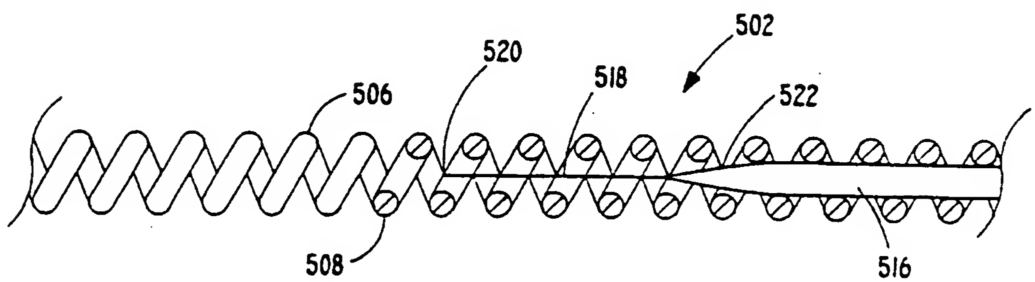

FIG. 5B

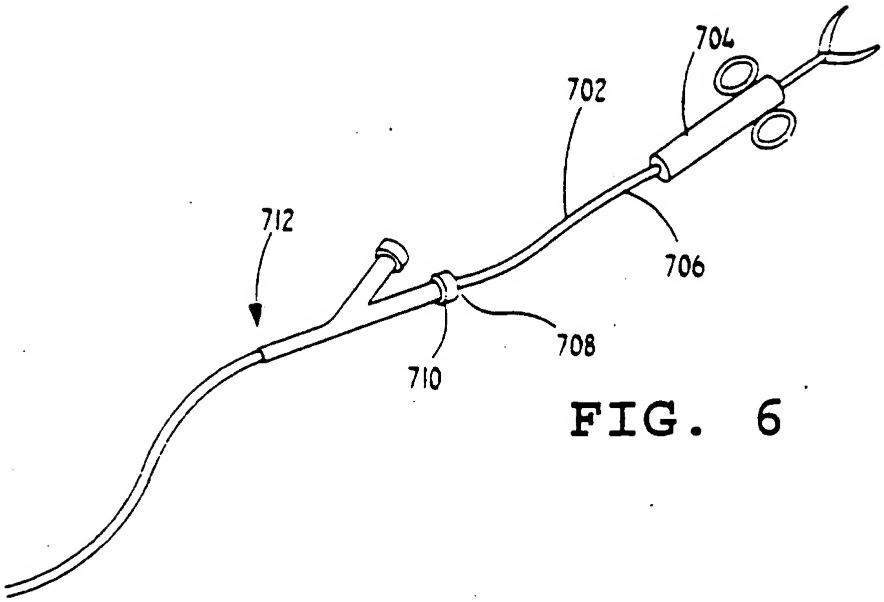

FIG. 6

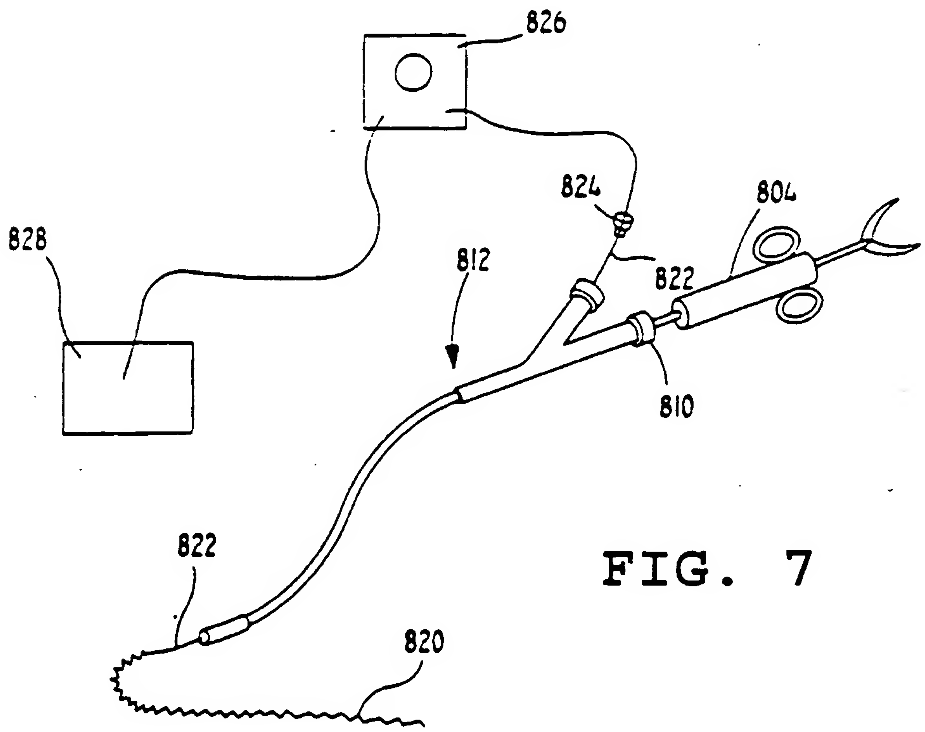

FIG. 7

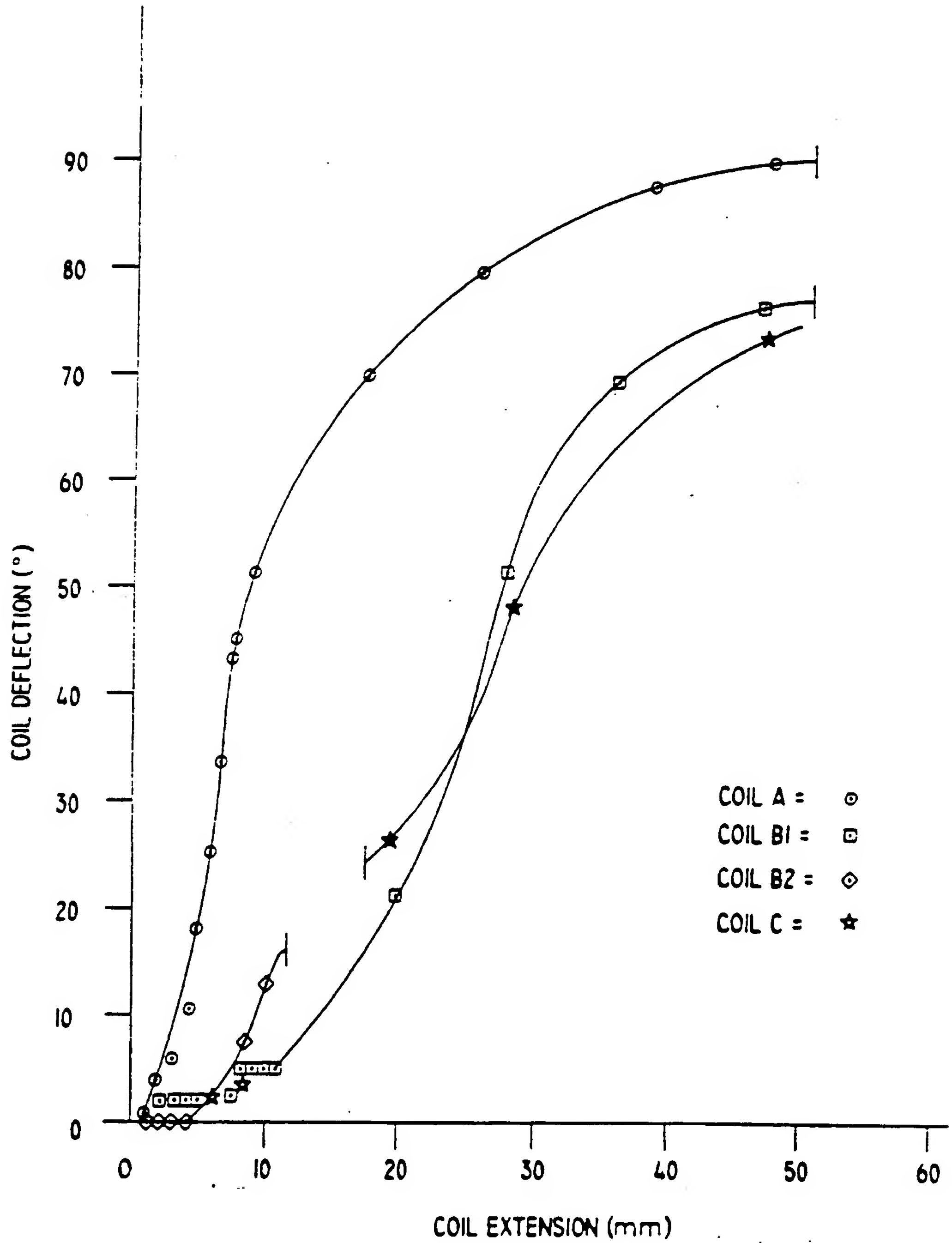
COIL DEFLECTION (°)
90
80
70
60
50
40
30
20
10
0
0
10
20
30
40
50
60
COIL EXTENSION (mm)
COIL A =
COIL B1 =
COIL B2 =
COIL C =

FIG. 8